K091908

JUL 10 2009

As required by 21 CFR 807.92 (c) this 510(k) summary is prepared

Application Date:

8th May 2009

Applicant:

Spectrum Medical LLP
Harrier 4,
Meteor Business Park,
Cheltenham Road East,
Gloucester.
GL2 9QL
United Kingdom

Official Correspondent:

Mr. Steve Turner
Chief Executive Officer
Telephone: +44 (0) 1242 650121
Fax: +44 (0) 8452 808127
Email: Steve.Turner@spectrum-medical.com

Proposed Device:

Blood Gas Monitor
Trade Name: M3 Monitor
Classification Name: Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
21 CFR 870.4330, Product code: DRY

Predicate Devices:

K072131 Spectrum Medical - M3 Monitor.

K940651 Sarns - Ultrasonic Air Sensor

Description of Proposed Device:

The Spectrum M3 Monitor consists of a 10.4 inch high definition touch screen and five active measuring channels mounted into a flat panel unit. Sensor cables are used to connect the active measuring channels to the external surface of extracorporeal blood line tubing. Two active measuring channels are used to measure venous and arterial oxygen saturation. The sensor cable head contains a light emitting diode that sends light through the extracorporeal tube, which illuminates the blood. The reflected spectra is collected by a fibre optic cable and quantified by a photo detector contained within a spectrometer. These spectra are compared to reference spectra by the monitor's software to determine the oxygen saturation of the blood. The third active measuring channel is used to measure hematocrit or haemoglobin concentration. The sensor cable head contains a light emitting diode that transmits near-infra-red light through the extracorporeal tube. A

photo diode measures a received light level. The level of signal attenuation is used to calculate hematocrit or haemoglobin concentration.

Three further active and optional measuring channels (i.e. the fourth, fifth and sixth channels) are used to measure simultaneously blood flow and the presence of emboli. Flow measurement is accomplished by measuring the difference in transit time between a pair of upstream and down stream ultrasonic transducers. Emboli is measured by detecting reductions in the amplitude of the ultrasonic signal.

Parameter values are displayed in both a digital and trended format. The M3 Monitor has been designed to self-detect the selected sensor and to automatically configure the required parameter display screens. The device can be configured by the trained clinician to set parameter specific alarms and to select either the display of hematocrit or haemoglobin concentration. Session data can be stored to a memory card supplied with the system, via a RS232 link or wirelessly to a remote computer.

The M3 Monitor is powered from the AC Mains supply and also incorporates a battery back-up that automatically switches on in the event of an interruption to the mains power supply. The system weighs 4.5 kg and is supplied with a pole mount clamp.

Intended Use of Proposed Device

The intended use of the M3 Monitor is for the non-invasive continuous monitoring of oxygen saturation, hematocrit and haemoglobin concentration, blood flow and gaseous emboli in the extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarm levels.

Summary of Technological Characteristics

Oxygen Saturation, Hematocrit / Haemoglobin Concentration and Flow:-

The proposed device has the same technological characteristics as the predicate M3 monitor cleared under 510(k) K072131. Although the proposed device can now be configured to offer up to three flow channels compared with the predicates single channel capability.

Emboli:-

There is no difference between the proposed device and predicate device in that both devices use the same ultrasonic technology. However with the proposed device the ultrasonic signal disruption software has been significantly developed to better quantify gaseous emboli with greater levels of precision.

Substantial Equivalence Determination

The M3 Monitor has an intended use that is also featured in its two predicate devices. Performance data has been provided to show that the revised M3 Monitor can measure the oxygen saturation, hematocrit / haemoglobin concentration, the flow of blood and gaseous emboli in an extracorporeal circuit to an equivalent or

improved accuracy when compared to the predicate devices. The M3 Monitor is therefore considered substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2009

Spectrum Medical Ltd.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories Inc.
12 Laboratory Drive
Research Triangle, NC 27709

Re: K091908
M3 Monitor
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II (two)
Product Code: DRY, KRL
Dated: June 23, 2009
Received: June 25, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091908

Device Name: M3 Monitor

Indications For Use:

The intended use of the M3 Monitor is for the non- invasive continuous monitoring of oxygen saturation, hematocrit and haemoglobin concentration, blood flow and gaseous emboli in an extracorporeal circuit.

The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number k091908